UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,609	10/09/2001	Shlomo Gabbay	SHEP5010US	8158

26294 7590 09/17/2008

TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P.
1300 EAST NINTH STREET, SUITE 1700
CLEVEVLAND, OH 44114

EXAMINER	
PELLEGRINO, BRIAN E	

ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
09/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte SHLOMO GABBAY

Appeal 2008-4369
Application 09/973,609
Technology Center 3700

Decided: September 17, 2008

Before TONI R. SCHEINER, LORA M. GREEN, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge.*

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 21-28, 51, 52, and 61-70. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to an implantation system for delivering a heart valve prosthesis. Claim 51 is representative of the claims on appeal, and reads as follows:

51. An implantation system, comprising:

an elongated cylindrical member having spaced apart ends, at least one of the ends providing an opening;

a body portion from which the cylindrical member extends to terminate in the opening that is spaced longitudinally apart from the body portion, the body portion having a greater outer diameter than the cylindrical member, the cylindrical member having an inner diameter in a range from about 5 mm to about 15 mm, the cylindrical member and body portion being substantially coaxial along a linear axis extending through the cylindrical member and the body portion;

a heart valve prosthesis including a generally cylindrical support having axially spaced apart ends, a valve mounted within the support at a fixed axial position between the spaced apart ends of the support, the prosthesis being deformable to a first condition in which the prosthesis has a reduced cross-sectional dimension, the support being biased to expand the prosthesis radially outwardly from the first condition to a second condition in which the prosthesis has a cross-sectional dimension that is greater than the reduced cross-sectional dimension, the prosthesis being mounted within the cylindrical member in the first condition; and

a plunger operative to traverse at least part of the cylindrical member and urge the prosthesis from the cylindrical member through the opening.

The Examiner relies on the following references:

Stevens	US 5,370,685	Dec. 6, 1994
Vesely	US 5,549,665	Aug. 27, 1996
Del Toro	US 5,733,267	Mar. 31, 1998
Torossian	US 5,851,210	Dec. 22, 1998
Shokoohi	US 6,077,296	Jun. 20, 2000

We reverse.

ISSUE (Obviousness)

The Examiner contends that claims 21, 28, 51, 61-63, 67, and 70 are obvious over the teachings of Stevens.

Appellant contends that the Examiner has failed to show reasons why the ordinary artisan would modify the teachings of Stevens to arrive at the claimed invention.

Thus, the issue on Appeal is: Has the Examiner provided sufficient reasons and/or evidence as to why the ordinary artisan would modify the teachings of Stevens to arrive at the claimed invention?

FINDINGS OF FACT

FF1 The invention relates to an improved heart valve prosthesis and methods of implanting the prosthesis that are efficient and less invasive (Spec. 2).

> The heart valve prosthesis is inserted into a generally cylindrical and elongated enclosure, such that the prosthesis has a reduced cross-sectional dimension generally corresponding to an internal dimension of the cylindrical enclosure. An opening is formed in a blood vessel and the portion of the enclosure holding the prosthesis is inserted through the opening. The cylindrical enclosure is positioned at a desired position and the prosthesis is discharged from the enclosure. As a result, the discharged heart valve prosthesis expands from the reduced cross-sectional dimension to an expanded cross-sectional dimension, such that an exterior portion of the heart valve prosthesis engages adjacent tissue to mitigate axial movement of the prosthesis relative to the adjacent tissue. The method can be performed without cardiopulmonary bypass as well as without opening the patient's heart.

(Spec. 3.)

FF2 Figure 19 of the Specification is reproduced below.

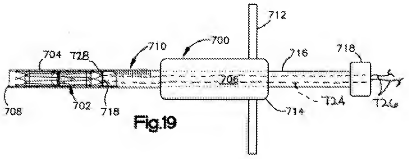

Fig.19

Figure 19 shows an implanter apparatus, 700, that may be used to implant a heart valve prosthesis, 702 (Spec. 26).

FF3 The implanter includes a cylindrical barrel, 704, which extends from the body 706, and terminates in an open end 708 (*id.*).

FF4 The implanter further includes a plunger 716, the plunger having an elongated portion extending from its distal end 718 and terminating in the proximal end 718 (*id.* at 27).

FF5 The Examiner rejects claims 21, 28, 51, 61-63, 67, and 70 under 35 U.S.C. § 103(a) as being obvious over Stevens (Ans.[1] 4).

FF6 The Examiner relies on Figures 9 and 10 of Stevens (Ans. 4-5), reproduced below.

[1] All references to the Answer are to the Examiner's Answer dated October 19, 2007.

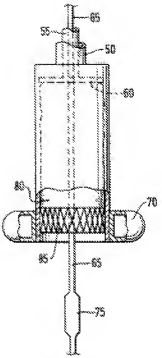

FIG. 9

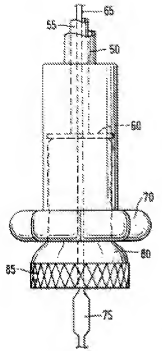

FIG. 10

Figure 9 shows a side view of the valve introducer capsule of Stevens, wherein balloons are passed over a guide wire, and Figure 10 shows a pusher disc advancing a valve out of the introducer capsule (Stevens, col. 3, ll. 19-22).

FF7 According to the Examiner, the implantation system of Stevens has a body portion (essentially indicated by 70) and a cylindrical member extending from the body portion (Ans. 5). Also included is a heart valve prosthesis with a generally cylindrical support 85. As can be seen in the Figures, the system also includes a plunger 60 to urge the prosthesis from the cylindrical member (*id.*).

FF8 The Examiner acknowledges that "Stevens fails to disclose the cylindrical member extends to terminate in an opening spaced longitudinally apart from the body member." (Ans. 5-6.)

FF9 Stevens teaches that an advantage of the system is "the ability to replace or supplant existing cardiac or other valves or prosthesis via a sutureless endovascular means avoiding the riskier, more expensive and complicated open heart surgical procedure." (Stevens, col. 5, ll. 2-5.)

FF10 The introducer capsule is made so that it can easily be maneuvered easily through the vasculature, and is introduced over a guide wire to the desired site (Stevens, col. 5, ll. 29-46).

FF11 Thus, Figures 9 and 10 show a guide wire 65 and a mounting balloon 75 (Stevens, col. 8, ll. 29-40).

FF12 As to the bracer 70, Stevens teaches:

> The bracer (**70**) is circumferentially attached to the external surface of the introducer capsule at the capsule's proximal end. The bracer comprises a differentially expandable device, such as a series of segmented balloons, and is characterized as having the capability of expanding to hold the introducer capsule in a precise position during delivery of the prosthetic valve device (FIG. **8**). Each segmented balloon can have an inflation/deflation channel to provide autonomous segmental expansion and compression. Differential expansion of the series of segmented balloons is directed from a central external control as done with the intraluminal procedure devices. Inflation of each differentially allows accurate positioning of the introducer capsule in proximity to the desired site of valve placement.

(Col. 7, ll. 38-52.)

PRINCIPLES OF LAW

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993) (citations omitted). In order to determine whether a prima facie case of obviousness has been established, we consider the factors set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966): (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the relevant art; and (4) objective evidence of nonobviousness, if present.

Moreover, "[o]ften, it will be necessary . . . to look to interrelated teachings of multiple [references] . . . and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed[.]" *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-41 (2007). "[T]his analysis should be made explicit" (*id.* at 1741), and it "can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" (*id.*).

ANALYSIS

The Examiner concludes:

> It would have been an obvious expedient to have the cylindrical member terminate apart from the body member such that it enables the surgeon to deliver the prosthesis to an area that is at

> a distance from the area where the delivery device can be stabilized for the surgeon to precisely place the implant. It is often difficult to stabilize the delivery catheter device where deployment occurs or at the opening of the cylindrical member, thus the provision of a stabilizing member at a distance or apart from the delivery opening can be advantageous such that it is enables stabilization in a location of a vessel and the surgeon is provided with the precision necessary by not having the cylindrical member move.

(Ans. 6.)

Appellant argues that the "Examiner has failed to show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." (App. Br.[2] 10-11.) According to Appellant, Stevens teaches that "the bracer (70), which comprises a differentially expandable device, such as a series of segmented balloons, is circumferentially attached to the external surface of the introducer capsule at the capsule's proximal end." (Reply Br. 5 (citing Stevens, col. 7, ll. 38-42).)

The Examiner appears to equate the bracer 70 of Stevens with a stabilizing member, reasoning that "the provision of a stabilizing member at a distance or apart from the delivery opening can be advantageous such that it is [sic] enables stabilization in a location of a vessel and the surgeon is provided with the precision necessary by not having the cylindrical member move." (Ans. 6.) However, as taught by Stevens, the bracer 70 is the proximal end of the introducer capsule and is made up of segmented

[2] All references to the Appeal Brief are to the Brief dated June 27, 2007.

balloons that allow the introducer capsule to be held in precise position for the delivery of the prosthetic valve device, allowing accurate positioning of the introducer capsule in proximity to the desired site of the valve replacement (FF12). The Examiner has not provided reasoning or evidence, given the above teaching of Stevens, that is, that the bracer 70 allows for accurate positioning at the desired site of placement of the valve prosthesis, as to why the ordinary artisan would thus move it back away from the cylindrical end.

Thus, we agree with Appellant, and conclude that the Examiner has failed to set forth a prima facie case of obviousness, and the rejection is reversed.

CONCLUSIONS OF LAW

We conclude that the Examiner has not provided sufficient reasons and/or evidence as to why the ordinary artisan would modify the teachings of Stevens to arrive at the claimed invention, and thus has failed to set forth a prima facie case of obviousness, and the rejection is reversed.

The Examiner also rejects claim 52 under 35 U.S.C. § 103(a) over the combination of Stevens and Torossian (Ans. 6-7); claims 22-26, 65, 66, 68, and 69 under 35 U.S.C. § 103(a) as being obvious over the combination of Stevens and Shokoohi (Ans. 7); claim 27 under 35 U.S.C. § 103(a) over the combination of Stevens and Vesely (Ans. 7-8); and claim 64 under 35 U.S.C. § 103(a) over the combination of Stevens and Del Toro (Ans. 8). As each rejection relies on Steven as discussed above, and as none of the secondary references remedies the deficiencies of Stevens, these rejections are also reversed.

REVERSED

cdc

TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P.
1300 EAST NINTH STREET, SUITE 1700
CLEVEVLAND OH 44114